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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,393	08/01/2003	Brian McKeown	13428-US	2918

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EXAMINER

WHALEY, PABLO S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/632,393	Applicant(s) MCKEOWN ET AL.	
	Examiner Pablo Whaley	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-61 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I: Claims 1-48, 53, and 54 drawn to methods of performing primer extension reactions, classified in class 702, subclass 019. If this Group is elected, then the below summarized four specie elections are also required.

Group II: Claim 49 drawn to a composition comprising a primer having a region capable of hybridizing to target nucleic acids, classified in class 536, subclass 24.33.

Group III: Claims 51-52 drawn to a method of monitoring the efficiency of incorporation of chain terminators into primers in a primer extension reaction, classified in class 435, subclass 006.

Group IV: Claims 55-59 drawn to method of screening animals for susceptibility to a disease or disorder, classified in class 435, subclass 006.

Group V: Claims 60-61 drawn to methods of breeding scrapie-resistant sheep comprising: determining the identity of polymorphic nucleotides, classified in class 800, subclass 008.

The inventions are distinct and divergent, each from the other because of the following reasons:

The inventions of Groups [III, IV, and V] are independent inventions because they are directed to different methods regarding critical limitations therein. Group V is drawn to a method of monitoring the efficiency of incorporation of chain terminators into primers in a primer extension reaction. Group VI is drawn to method of screening animals for susceptibility to a disease or disorder. Group VII is drawn to methods of breeding scrapie-resistant sheep, comprising determining the identity of polymorphic nucleotides. These methods are generally separately analyzed and published, and thus document the undue search burden if searched together.

The inventions of Group I and Groups [III, IV, and V] are independent inventions because they are directed to different methods regarding critical limitations therein. Group I is drawn to methods of performing primer extension reactions, which are independent from the methods of Groups [III, IV, and V] for reasons previously discussed. Critical features of Group I that are distinct from Groups [III, IV, and V] include the limitations of obtaining a sample comprising target nucleic acid from one or more individuals, obtaining an amplicon population, and generating an amplicon population comprising a ratio 1:1 and a ratio of 3:1 with respect to the identity of the nucleotides. These methods are generally separately analyzed and published, and thus document the undue search burden if searched together.

The inventions of Group II and Groups [I, III, IV, and V] are independent inventions because Group IV is directed to a composition comprising a primer having a region capable of hybridizing to target nucleic acids, whereas Groups [I, III, IV, and V] are directed to different methods regarding critical limitations therein.

Thus, the search for these groups together would present an undue search burden as they are directed to methods and electronic devices that are generally distinct and separate.

SPECIE ELECTION REQUIREMENT FOR GROUP I

This application contains claims directed to patentably distinct species of the claimed invention. If Group I is elected, the applicant is further required to make the following four specie elections for purposes of examination:

Specie A1: Species of positions of invariant nucleotides with respect to variant nucleotides are cited in claims 2-5, which are generally separately classified and published, and thus document undue search burden if searched together. Thus applicants are required to select a position of the invariant nucleotide with respect to a variant nucleotide from those listed in claims 2-5.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1, 6-48, 53, and 54 are generic to the above species.

Specie A2: Species of detection characteristics are cited in claim 14, which are generally separately classified and published, and thus document undue search burden if searched together. Thus applicants are required to select a type of detection characteristic from those listed in claim 14 to begin examination.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-13, 15-35, 37-48, 53, and 54 are generic to the above species.

Specie A3: Species of arrays are cited in claims 20 and 21, which are generally separately classified and published, and thus document undue search burden if searched together. Thus

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applicants are required to select a type of array from those listed in claims 20 and 21.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-19, 22-41, 44-48, 53, and 54 are generic to the above species.

Specie A4: Species of variant nucleotides on the same versus different nucleic acid molecules are cited in claims 12 and 13, which are generally separately classified and published, and thus document undue search burden if searched together. Thus applicants are required to select a variant nucleotide location from those listed in claims 12 and 13.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-11, 14-33, 36-48, 53, and 54 are generic to the above species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am through 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
11/17/05